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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,872	08/27/2001	Jean Ackermann	20757	4842

151 7590 09/11/2002

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/11/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,872

Applicant(s)

Ackermann, J. et al.

Examiner

CHARANJIT AULAKH

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug. 5, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 and 60-75 is/are pending in the application.
- 4a) Of the above, claim(s) 9, 28-41, and 64-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-27, 42-58, 60-63, and 67-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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DETAILED ACTION

1. According to paper no. 10 filed on Aug. 5, 2002, the applicants have canceled claim 59 and furthermore, amended claims 1, 24, 25, 43, 44, 47, 49, 51, 53-56, 58, 61, 68, 71, 73 and 75.
2. Claims 1-58 and 60-75 are now pending in the application. Claims 9, 28-41 and 64-66 remain withdrawn from further consideration as being drawn to non-elected invention.

Response to Arguments

3. Applicant's arguments filed on Aug. 5, 2002 (paper no. 10) regarding restriction requirement as well as indefiniteness have been fully considered but they are not persuasive. The instant compounds of formulae (I) and (Ia) encompass hundreds of thousands of compounds based on the values of variables V, A1-A5, m and n. The value of variable n can be 0-7 and variable V can be four different groups. Therefore, the central core of the instant compounds is variable W attached to the N of the piperidine ring and therefore, is critical for the common core of the instant compounds. By having value of variable W as SO₂ and SO₂NH, the applicants are not limited to one or two species but on the contrary still encompass hundreds of thousands of compounds based on variables A1-A5, U, V, M and n variables. As stated in the last office action and mentioned above, variable W is critical for the common core and burdensome search. Therefore, restriction requirement as indicated is proper and thereby made final.

In regard to indefiniteness of the term --esters---, the examiner does not agree with the applicants arguments that the specification teaches preparing esters of the

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instant compounds. There is not even a single example showing esters of the instant compounds in the specification. There is no teaching in the specification that esters prepared from the instant compounds having optionally substituted variables with hydroxy groups will work effectively in vivo.

Conclusion

4. Rejections of claims 1-8, 10-27, 42, 45, 46, 48, 50, 52, 57, 60, 62, 63, 67, 69, 70 and 72-75 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.

5. Objections of claims 1-7, 10-27, 42, 60, 62, 63 and 73-75 due to Improper Markush Group is maintained for the reasons of record.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-6, 8-27, 42-44, 59-63, 67-71 and 73-75 are rejected under 35 U.S.C. 102(a) as being anticipated by Aebi (U.S.Patent no. 6,034,275, cited on applicants form 1449).

Aebi discloses tertiary amines. The compounds of formula Ie (see column 10, lines 40-60 as well as examples 49 and 50) and a method of using them for treating various disorders (see col. 22,

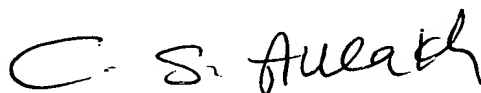
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lines 54-64) disclosed by Aebi anticipate the instant claims when W or X represents SO₂, n is 0 and V represents O in the instant compounds of formulae (I) and (Ia).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.



CHARANJIT S. AULAKH

PRIMARY EXAMINER